DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 7, 2015

National Advanced Endoscopy Devices, Inc.
Gayle Butler
Compliance Manager
22134 Sherman Way
Canoga Park CA 91303

Re: K141515
Trade/Device Name: AED Hysteroscope And Accessories
Regulation Number: 21 CFR 884.1690
Regulation Name: Hysteroscope and accessories
Regulatory Class: II
Product Code: HIH
Dated: November 24, 2014
Received: December 4, 2014

Dear Gayle Butler,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -A

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141515

Device Name
AED Hysteroscope and Accessories

Indications for Use *(Describe)*
AED Hysteroscope and Accessories are used to permit direct viewing of the cervical canal and the uterine cavity for the purpose of performing diagnostic and surgical procedures.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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National Advanced Endoscopy Devices, Inc. Premarket Notification: K141515

510(k) Summary of Safety and Effectiveness

Date: **December 22, 2014**

Submitter:

National Advanced Endoscopy Devices, Inc.
22134 Sherman Way
Canoga Park, CA 91303
Telephone: 818.227.2720
Fax: 818.227.2724
Contact Person: Gayle M. Butler
Compliance Manager

Product:

Trade Name:	AED Hysteroscope and Accessories
Classification:	Class II
Common Name:	Hysteroscope and Accessories
Classification Name:	Hysteroscope (And Accessories) (HIH, 21 CFR 884.1690)

Predicate Devices:

Karl Storz Fixed Magnification Telescope/KS Variable Magnification Telescope K935716

Device Description:

AED Hysteroscopes

5705B AED Hysteroscope
4.0mm diameter, 30^0 Angle of View, 36cm length, 30cm working length

5729B AED Hysteroscope
2.9mm diameter, 30^0 Angle of View, 36cm length, 30cm working length

AED Sheaths

Examination Sheaths

18-2305 for use with a 4.0mm diameter, 30^0 Angle of View Hysteroscope
5.0mm diameter, 31cm length, 26cm working length, 1 stopcock

18-2306 for use with a 2.9mm diameter, 30^0 Angle of View Hysteroscope
4.0mm diameter, 31cm length, 26cm working length, 1 stopcock

18-2304 Continuous Flow for use with a 2.9mm diameter, 30^0 Angle of View Hysteroscope
Inner Sheath: 3.8mm diameter, 27cm length, 25cm working length, 1 stopcock
Outer Sheath: 4.5mm diameter, 24cm length, 18cm working length, 1 stopcock

18-2309 Continuous Flow for use with a 4.0mm diameter, 30^0 Angle of View Hysteroscope
Inner Sheath: 5.2mm diameter, 27cm length, 25cm working length, 1 stopcock
Outer Sheath: 6.2mm diameter, 24cm length, 18cm working length, 1 stopcock

18-2313 5.1mm diameter, 1 luer lock adapter
5.1mm diameter, 31cm length, 26cm working length, 1 stopcock with luer adapter

18-2314 5.1mm diameter, 1 luer lock adapter, rotatable
5.1mm diameter, 31cm length, 26cm working length, 1 rotatable stopcock with luer adapter

Examination/Operative Sheaths

18-2300 for use with a 4.0mm diameter, 30^0 Angle of View Hysteroscope
1 Instrument Channel and 1 Rotatable Stopcock
5.0mm diameter, 31cm length, 22cm working length, 2.0mm Channel Diameter

18-2302 for use with a 2.9mm diameter, 30^0 Angle of View Hysteroscope
1 Instrument Channel and 1 Rotatable Stopcock
4.0mm diameter, 31cm length, 22cm working length, 2.0mm Channel Diameter

18-2307 for use with a 4.0mm diameter, 30^0 Angle of View Hysteroscope
1 Instrument Channel and 2 Stopcocks
5.0mm diameter, 31cm length, 22cm working length, 2.0mm Channel Diameter , Continuous Flow

18-2308 for use with a 2.9mm diameter, 30^0 Angle of View Hysteroscope
1 Instrument Channel and 2 Stopcocks
4.0mm diameter, 31cm length, 22cm working length
2.0mm Channel Diameter, Continuous Flow

The AED Hysteroscope and Accessories is a reusable surgical device that incorporate operative and examination sheaths.

The AED Hysteroscope is a reusable rod lens Hysteroscope consisting of an eyepiece lens and a light post connection for fiber optic light cables. A shaft composed of surgical grade stainless steel encloses the glass rod-lens system and a built-in fiber optic light carrier made of glass/acrylic. The light post body is also comprised of surgical stainless steel. The eyepiece is made from Ultem.

Examination Sheaths are designed to be used with a hysteroscope alone. An operative sheath is an examination sheath with one or more instrument channels. The operative and examination sheaths are composed of surgical grade stainless steel with the exception of a Fixing Ring (where applicable) which is composed of Nylon.

There are two designs for Continuous Flow Sheaths. One design consists of a single sheath with two interior channels (18-2307 and 18-2308) for the inflow and outflow of media to be used with the hysteroscope alone. Alternatively, an inner and outer sheath may be used to perform the same function (18-2304 and 18-2309).

The device is reusable and provided non-sterile. It must be cleaned and sterilized before use.

Indication for Use:

AED Hysteroscope and Accessories are used to permit direct viewing of the cervical canal and the uterine cavity for the purpose of performing diagnostic and surgical procedures.

Comparison of Technological Characteristics:

The AED Hysteroscope and Accessories has the same fundamental technological characteristics as the predicate devices and is substantially equivalent in design, materials and intended use as the predicate devices.

Karl Storz Fixed Magnification Telescope/KS Variable Magnification Telescope (K935716):

- Same Indications for Use
- Utilizes the Same Operating Principle
- Same Basic Mechanical Design
- Manufactured Using the Same Materials

The AED Hysteroscope and Accessories differ from the predicate device Karl Storz Fixed Magnification Telescope/KS Variable Magnification Telescope (K935716):

- The KS Variable Magnification Telescope has an adjustable ocular lens that can, using an exterior knob, be moved to adjust magnification to 80x. The AED Hysteroscope has a fixed nonadjustable ocular lens.

There is no difference between the Karl Storz Fixed Magnification Telescope and the AED Hysteroscope.

Performance Testing:

Testing was performed according to IEC 60601-2-18. Thermal testing and simulated use testing were performed to support safety and effectiveness and substantial equivalence to the predicate devices. The AED Hysteroscope and Accessories met all specified design and performance requirements.

Performance Standards:

The device conforms to ISO 8600-4:2014, 8600-1:2013, 8600-3:1997 Amendment 1 2003, 8600-5:2005, 8600-6:2005 and IEC 60601-2-18 (1996) and IEC 60601-2-18 Edition 3.0 2009-08.

Conclusion: Based on the technical information, intended use and performance information provided in this premarket notification, the **AED Hysteroscopes and Accessories** have been shown to be substantially equivalent to the current legally marketed predicate devices.